







TP Orthodontics Tooth Positioning Appliances

The products covered by this instruction include:

- Refine® Aligners
- Refine Finishing Appliance
- Original Tooth Positioner
- Mini-Positioner

Symbols Used on Labeling

	Manufacturer.
	Caution! See warnings and precautions.
	Consult instructions for use.
	Do not re-use.
	Medical device.
	Prescription device.

Indications for Use

TP Orthodontics Tooth Positioning Appliances consist of plastic appliances (one or more) indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, TP Orthodontics Tooth Positioning Appliances sequentially position teeth by way of continuous gentle force.

This appliance is intended for use in orthodontic treatment.

Warnings

- This product is intended for single patient use. Its reuse may cause cross contamination, loss of material integrity, and compromise overall product safety and performance.

Precautions

- Assess existing crowns and bridges prior to initiating treatment with the tooth positioning appliances as these can become dislodged during treatment and require replacement or re-cementation.
- Tooth positioning appliances are not effective in the movement of dental implants.
- Appliance fit may be affected by missing, erupting or irregularly shaped teeth or by not performing interproximal reduction as determined in the prescription.
- Do not trim appliances to prevent unwanted tooth movement.
- Keep appliances away from hot water and harsh chemicals.
- Always store appliances in a cool, dry place.

Contraindications

- Appliance use by patients with compromised oral health, such as poor oral hygiene, periodontal disease, or preexisting dental conditions (i.e. decalcification, carious lesions, large restorations) can increase the risk of tooth damage.

Instructions for Use


This product must be used by qualified orthodontists or dentists trained in orthodontics.

Appliance Delivery / Placement

- Rinse new appliance with cold water prior to delivering/ using them.
- Review appliance use routine and care with the patient.
- Place appliance and assess if there is any tissue impingement.
- Perform any pre-determined interproximal reduction.
- Monitor teeth movement and treatment progress at follow-up visits.
- Dispense appliances as deemed appropriate and inform patient of when to change appliance if applicable.
- The use of retainers is advised at the end of treatment.

Appliance Recommendations to Provide to Patients: Aligners

- Aligners must be worn most of the day (20-22h), being removed only for eating, drinking and performing oral hygiene. Failure to wear the aligners as prescribed may lengthen treatment time.
- The aligners are marked with their sequencing order and they should be worn in an increasing numerical order.
- The aligners should be replaced every 2-3 weeks as prescribed by the doctor.
- Initiate the use of a new aligner set at night before going to bed to improve initial discomfort.

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Appliance Recommendations to Provide to Patients: Tooth Positioning Appliances (All)

- Do not place the appliances under hot water or leave them in the heat as this would distort the appliance.
- When appliances are not being used, keep them in their storage case to prevent them getting lost, misplaced or broken.
- Eating or drinking while wearing appliances or lack of oral hygiene increases the risk to developing dental caries, decalcification and periodontal disease.
- Alteration in the salivary flow (increase or decrease) may be experienced while in treatment.
- Clean appliances with a soft bristle brush and water; do not soak them in hot water, mouthwash or denture cleaners as these may damage these.
- After eating or drinking, it is recommended to brush teeth and appliance prior to having them re-inserted.

Matters Needing Attention, Caution and Reminder

- Caution: Federal law restricts this device to sale by or on the order of a dentist.
- This product is for single use only.
- For aligners: the tray number is identified in the package and on the aligner,

Storage Condition

Clean, dust-free, cool, dry area.

Product Performance Structure and Composition

Thermoplastic material

NOTICE:

TP Orthodontics, Inc. warrants that its products are free from defects in materials and workmanship. TPO's liability and the customer's sole remedy in the event of any claimed defect shall be limited to replacement of the product, or at TPO's discretion, refund of the purchase price. This warranty is in lieu of any other warranties, express or implied, including any implied warranty of merchantability, fitness for a particular purpose, or otherwise, and of any other obligations or liability on TPO's part. Other than the warranties listed above, under no circumstances will TPO be liable for any loss, damages arising in connection with use, or inability to use, TPO's products.



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